NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EVANGELINE BAKER et al., Plaintiffs, v. APP PHARMACEUTICALS LLP et al., Defendants.	Civil Action No. 09-05725 (JAP) **MEMORANDUM OPINION**

PISANO, Judge

This matter comes before the Court upon a Motion for Summary Judgment by defendant[1] Baxter Healthcare Corporation ("Baxter" or "Defendant") to dismiss Counts I, II, and VIII of plaintiffs Evangeline Baker ("Mrs. Baker") and Bruce Baker's (collectively "Plaintiffs") First Amended Complaint. (DE 74.) Plaintiffs oppose the Motion. (DE 82.) The Court has considered the parties' submissions and decided the matter without oral argument pursuant to Federal Rule of Civil Procedure 78. For the reasons set forth below, the Court will grant the Motion for Summary Judgment.

I. BACKGROUND

Mrs. Baker visited her primary care doctor complaining of chest pain on September 4, 2007. (Defendant's Statement of Undisputed Material Fact ("Def. SUMF") ¶ 27; DE 74-2.) Mrs. Baker was taken by ambulance to the Hunterdon Medical Center Emergency Room where a cardiac catheterization procedure revealed she had severe coronary artery disease. (Id. ¶ 28.)

[1] Defendants App Pharmaceuticals, LLC and Hospira World Wide Inc., doing business as Hospira Inc., are no longer parties to this action. (See DE 20, 64.)

Mrs. Baker was thereafter transferred to Morristown Memorial Hospital, and Dr. James Slater, a cardiac surgeon, performed a triple coronary bypass on Mrs. Baker on September 5, 2007. (Id. ¶ 4.)

During her hospital stay, Mrs. Baker was administered the commonly prescribed drug heparin. (Id. ¶ 31.) Heparin is an anticoagulant that prevents blood clots. (Id. ¶ 4.) But the drug is known to cause heparin induced thrombocytopenia ("HIT"), or low blood platelet count. (Id. ¶ 6.) HIT is an allergic reaction, which begins when antibodies attack heparin molecules bound to platelet factor 4 protein. (Plaintiffs' Counter Statement of Material Facts ("Pls. SUMF") ¶ 8; DE 81.) HIT may progress to a more serious adverse reaction called heparin induced thrombocytopenia and thrombosis ("HITT"). (Id.) HITT occurs when heparin antibodies activate blood platelets, which in turn cause blood clots. (Id.) HITT can lead to, among other things, deep vein thrombosis, stroke, heart attack, gangrene of the extremities, and possibly death. (Def. SUMF ¶ 22.)

Mrs. Baker received heparin during and after her surgery.[2] Dr. Slater administered a heparin drip during Mrs. Baker's coronary artery bypass surgery on September 5, 2007, (Pls. SUMF ¶ 13), and intravenous heparin flushes during the two days after surgery, (Def. SUMF ¶ 32). Mrs. Baker developed atrial fibrillation (a cardiac arrhythmia) on September 7th, and so heparin was reinitiated by Dr. Slater on September 11th and continued through September 14th.[3] (Id. ¶¶ 33, 34.) On September 11th, Mrs. Baker's platelet count was measured to be

[2] Mrs. Baker also received heparin during her cardiac catheterization at Hunterdon Medical Center, but that heparin was not manufactured by Baxter. (Def. SUMF ¶ 29.)

[3] In their opposition to Defendant's Statement of Undisputed Material Facts, Plaintiffs dispute that there is any evidence that heparin was reinitiated because of Mrs. Baker's atrial fibrillation. (Plaintiffs' Response to Defendant's Statement of Undisputed Material Facts ("Pls. RSUMF") ¶ 34; DE 81.) But Plaintiffs' expert, Dr. Stephen B. Shohet, inferred that heparin was reinstated due to the atrial arrhythmia. (Expert Report of Stephen Shohet, M.D. at 5, Pls. Ex. H to Poondi Decl.; DE 82-9.)

279,000/mm^3, which is normal. (Pls. SUMF ¶ 14.) However, by September 15th, her platelet count was down to 45,000/mm^3, alerting Mrs. Baker's physicians to the possibility of HIT. (Id. ¶¶ 14, 16.) Indeed, an HIT study confirmed that Mrs. Baker was positive for heparin antibodies. (Def. SUMF ¶ 37.) It is not known, however, at what point between September 11th and September 15th that Mrs. Baker's platelet count reached thrombocytopenic levels. (Id. ¶ 46; Pls. RSUMF ¶ 46.) That is because no one measured Mrs. Baker's platelet level during this time period, despite the hospital's stated protocol to monitor a patient's platelet count every three days in order to detect HIT. (Def. SUMF ¶¶ 41, 42, 44.)

Over the next several weeks, Mrs. Baker developed blood clots and gangrene in her left leg, confirming a clinical diagnosis of HITT. (Pls. SUMF ¶¶ 17, 18.) She required a partial amputation of her left foot in November 2007 and amputation of her left leg below the knee in February 2008. (Id. ¶ 19.) Plaintiffs thereafter sued several manufacturers of heparin, including Baxter, asserting various product liability claims.[4] Plaintiffs allege that Baxter, the only heparin manufacturer remaining in the action, was aware of but failed to adequately warn of the serious side-effects associated with heparin use.

Defendant's heparin was first approved by the United States Food and Drug Administration ("FDA") forty years ago. (Def. SUMF ¶ 5.) Before the FDA approves a drug, the manufacturer must show that the drug is safe and effective for its intended use. See 21 U.S.C. § 355. To do so, the manufacturer submits a new drug application ("NDA"), which includes, among other things, clinical trial data, a risk-benefit analysis, and proposed labeling. See 21 C.F.R. 314.50. Prescription drug labeling must "contain a summary of the essential scientific information needed for the safe and effective use of the drug." 21 C.F.R. 210.56(a)(1).

[4] Counts III, IV, V, VI, and VII of the First Amended Complaint as well as Plaintiffs' claim for punitive damages were dismissed on November 30, 2011. (DE 46.) Only Counts I, II, and VIII remain.

The FDA has the authority to enforce its labeling requirements, and may go so far as to withdraw approval for the drug if the drug's labeling is false, misleading, and/or contains inadequate warnings. See 21 U.S.C. § 352(a), (f); 21 U.S.C. § 355(e).

The parties agree that Defendant's heparin has always contained FDA-approved labeling, including risk disclosures and warnings. (Def. SUMF ¶ 5; Pls. RSUMF ¶ 5.) In 2001, the heparin label disclosed the risk of HIT and HITT in the "Precautions" section. (See Def. Ex. 3 to Miller Decl.; DE 74-7.) In 2005, Defendant submitted a supplemental NDA via the "changes being effected" process to include additional HIT and HITT information the "Warnings" section of its heparin labeling. See 21 C.F.R. 314.70. The FDA suggested several alterations, all of which Defendant incorporated into the labeling, and the FDA found the updated labeling "acceptable" in June 2007. (See Def. Ex. 7 to Miller Decl.; DE 74-12.) That labeling, the same labeling found on the heparin administered to Mrs. Baker, stated in the "Warnings" section:

> Thrombocytopenia
>
> Thrombocytopenia has been reported to occur in patients receiving heparin with a reported incidence of up to 30%. Platelet counts should be obtained at baseline and periodically during heparin administration . . . .
>
> Heparin-induced Thrombocytopenia (HIT) and Heparin-induced Thrombocytopenia Thrombosis (HITT)
>
> Heparin-induced Thrombocytopenia (HIT) is a serious antibody mediated reaction resulting from irreversible aggregation of platelets. HIT may progress to the development of venous and arterial thromboses, a condition referred to as Heparin-induced Thrombocytopenia and Thrombosis (HITT). Thrombotic events may also be the initial presentation for HITT. These serious thromboembolic events include deep vein thrombosis, pulmonary embolism, cerebral vein thrombosis, limb ischemia, stroke, myocardial infarction, mesenteric thrombosis, renal arterial thrombosis, skin necrosis, gangrene of the extremities that may

> lead to amputation, and possibly death. Thrombocytopenia of any degree should be monitored closely. If the platelet count falls below 100,000/mm^3 or if recurrent thrombosis develops, the heparin product should be promptly discontinued and alternative anticoagulants considered, if patients require continued anticoagulation.

(See Def. Ex. 6 to Miller Decl. at 5; DE 74-11.)

Plaintiffs claim that this labeling was inadequate and caused Mrs. Baker's injuries. In particular, Plaintiffs allege that Baxter's heparin product failed to warn of the dangers of heparin administration (Count I) and was defective in design because it did not have an adequate warning label (Count II). (See First Am. Compl.; DE 18.) In addition, Plaintiff Bruce Baker alleges loss of consortium resulting from his wife's injuries (Count VIII). (Id.) Defendant moved for summary judgment dismissing Counts I, II, and VIII on May 11, 2012. (DE 74.) Plaintiffs filed a brief in opposition on June 19, 2012. (DE 79, 82.) On July 9, 2012, Defendant filed a reply brief in further support of its Motion for Summary Judgment. (DE 86.)

II. STANDARD OF REVIEW

A court shall grant summary judgment pursuant to Rule 56 of the Federal Rules of Civil Procedure "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The substantive law identifies which facts are critical or "material." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A material fact raises a "genuine" issue "if the evidence is such that a reasonable jury could return a verdict" for the non-moving party. Healy v. N.Y. Life Ins. Co., 860 F.2d 1209, 1219 n.3 (3d Cir. 1988).

On a summary judgment motion, the moving party must show, first, that no genuine issue of material fact exists. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). If the moving party

makes this showing, the burden shifts to the non-moving party to present evidence that a genuine fact issue compels a trial. Id. at 324. The non-moving party must then offer admissible evidence that establishes a genuine issue of material fact, id., not just "some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). However, "a party who does not have the trial burden of production may rely on a showing that a party who does have the trial burden cannot produce admissible evidence to carry its burden as to the fact." Celotex Corp., 477 U.S. at 323.

The Court must consider all facts and their logical inferences in the light most favorable to the non-moving party. Pollack v. American Tel. & Tel. Long Lines, 794 F.2d 860, 864 (3d Cir. 1986). The Court shall not "weigh the evidence and determine the truth of the matter," but need determine only whether a genuine issue necessitates a trial. Anderson, 477 U.S. at 249. If the non-moving party fails to demonstrate proof beyond a "mere scintilla" of evidence that a genuine issue of material fact exists, then the Court must grant summary judgment. Big Apple BMW v. BMW of N. Am., 974 F.2d 1358, 1363 (3d Cir. 1992).

III. LEGAL STANDARD AND ANALYSIS

This is a diversity action, over which the Court has jurisdiction pursuant to 28 U.S.C. § 1332. (See First Am. Compl. ¶¶ 1, 2, 4.) It is well established that a federal court sitting in diversity must apply the substantive law of the state whose law governs the action. Erie R. Co. v. Tompkins, 304 U.S. 64, 78 (1938); Griggs v. Bic Corp., 981 F.2d 1429, 1431-32 (3d Cir. 1992). Here, the parties agree that the substantive law of New Jersey applies to all claims in this litigation.

In New Jersey, product liability actions are governed by the New Jersey Products Liability Act ("PLA"). N.J. Stat. Ann. §2A:58C-1, et seq. The New Jersey Legislature enacted

the PLA based on an "urgent need for remedial legislation to establish clear rules with respect to certain matters relating to actions for damages for harm caused by products." Id. § 2A:58C-1(a). In so doing, "[t]he Legislature intended . . . to limit the liability of manufacturers so as to balance [] the interests of the public and the individual with a view towards economic reality." Zaza v. Marquess & Nell, Inc., 675 A.2d 620, 627 (N.J. 1996). The New Jersey Supreme Court has observed that "[t]he language chosen by the Legislature in enacting the PLA is both expansive and inclusive, encompassing virtually all possible causes of action relating to harms caused by consumer and other products." In re Lead Paint Litigation, 924 A.2d 484, 503 (N.J. 2007).

A. Failure to Warn

In Counts I and II of their First Amended Complaint, Plaintiffs allege one of the causes of action covered by the PLA—failure to warn. The PLA provides that a manufacturer is "not liable for harm caused by a failure to warn if the product contains an adequate warning or instruction . . . ." N.J. Stat. Ann. 2A:58C-4. An "adequate" warning is "one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, . . . taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician. Id.

1. Presumption of Adequacy for Prescription Drug Labels

In failure to warn cases involving prescription drugs, "[i]f the warning or instruction given in connection with a drug . . . has been approved or prescribed by the federal Food and Drug Administration under the 'Federal Food, Drug, and Cosmetic Act,'" there is a rebuttable presumption that the warning is adequate. Id. This is no ordinary rebuttable presumption. "Compliance with FDA regulations" gives rise to "what can be denominated as a super-

presumption[.]" Kendall v. Hoffman-La Roche, Inc., 36 A.3d 541, 544 (N.J. 2012); see also Perez v. Wyeth Labs., Inc., 734 A.2d 1245, 1259 (N.J. 1999) ("[C]ompliance with FDA standards should be virtually dispositive of such claims."). Indeed, the PLA's presumption that an FDA-approved prescription drug label is adequate "is stronger and of greater evidentiary weight than the customary presumption referenced in [New Jersey Rule of Evidence] 301." Bailey v. Wyeth, Inc., 37 A.3d 549, 571 (N.J. Super. Ct. Law Div. 2008), aff'd sub nom. Deboard v. Wyeth, 28 A.3d 1245 (N.J. Super Ct. App. Div. 2011).

In this case, there is no dispute that Defendant's heparin labeling was approved by the FDA. (See Def. SUMF ¶ 5; Pls. RSUMF ¶ 5.) In 2005, Baxter submitted updated labeling for its heparin products. The FDA suggested several alterations, which Baxter incorporated, and in June 2007, the FDA found the labeling acceptable. Therefore, Defendant is entitled to the statutory presumption that its heparin labeling satisfied its duty to warn.

2. Rebutting the Presumption of Adequacy

Plaintiffs can rebut the "super-presumption" with evidence of "intentional misconduct by the manufacturer." Bailey, 37 A.3d at 569. First, a plaintiff may introduce evidence of "deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects" by the pharmaceutical company, (the "Perez exception"). Perez, 734 A.2d at 1259. Second, a plaintiff may introduce substantial evidence of "economically-driven manipulation of the post-market regulatory process," (the "McDarby exception"). McDarby v. Merck & Co., Inc., 949 A.2d 223, 256 (N.J. Super. Ct. App. Div. 2008).

a. The Perez Exception

Plaintiffs argue that the Perez exception applies here to rebut the presumption of adequacy because Defendant failed to disclose relevant information to the FDA when Defendant

sought to alter the label in 2005. According to Plaintiffs, had Defendant supplied such information to the FDA, the label would have contained warnings that would have prevented Mrs. Baker's injuries. In particular, Plaintiffs conclude that Defendant failed to disclose the following:

> (1) most HIT cases (approximately 70%) present where heparin is re-administered 4-10 days after initial heparin exposure;
>
> (2) there is an increased risk of HIT between days 4 to 14 of administration;
>
> (3) surgical patients and those in critical care units are much more likely to develop HIT;[5]
>
> (4) platelet counts should be performed prior to initiating heparin therapy;[6]
>
> (5) platelet counts should be monitored at least every other day between 4 and 14 days after initial exposure to heparin in post-operative patients receiving unfractionated[7] heparin; and
>
> (6) low molecular weight heparin has less propensity to cause HIT in comparison to unfractionated heparin.

(Pls. Br. at 16; DE 82.)

The Court finds that Plaintiffs have failed to demonstrate how these six principles raise a genuine fact issue necessitating a trial. First, Plaintiffs present no evidence that Defendant

[5] It is not clear to whom Plaintiffs are comparing surgical and critically ill patients. Heparin is used in patients with serious conditions such as deep vein thrombosis, pulmonary embolism, disseminated intravascular coagulation and in patients undergoing abdominothoracic or cardiac surgery. (See Def. Ex. 6 to Miller Decl. at 4 ("Indications and Usage").) Thus, it makes sense that the patient population in which heparin is indicated would be the patient population more likely to develop an adverse reaction to HIT as compared to any other patient population.

[6] The heparin label provides, "Platelet counts should be obtained at baseline . . . ." (See Def. Ex. 6 to Miller Decl. at 5.) Therefore, Plaintiffs cannot seriously contend that Defendant failed to disclose that platelet counts should be performed before initiating heparin, as this is plainly stated on the heparin label.

[7] There are two forms of heparin: unfractionated heparin and low molecular weight type heparin. (See Francis Expert Report at 1-2; Pls. Ex. B to Poondi Decl.; DE 82-3.)

intentionally withheld or concealed this information. Significantly, all of the information Plaintiffs accuse Defendant of withholding was publicly available in published scientific and medical literature. See Bailey, 37 A.3d at 577 (noting the lack of intent to conceal risks where those risks were included in the worldwide medical literature); see also Chambers v. G.D. Searle & Co., 441 F. Supp. 377, 384 (D. Md. 1977) (directed verdict granted in favor of the defendant drug manufacturer where "[t]here was no other information available to defendant indicating greater risks or dangers than what was" reviewed by the FDA). Plaintiffs therefore cannot demonstrate intentional concealment or nondisclosure by pointing only to information that was widely available to the scientific and medical community.

The second problem with Plaintiffs' argument is that Defendant did in fact disclose much of what Plaintiffs claim was deliberately concealed or withheld. When submitting its proposed updated label to the FDA in 2005, Baxter included several scientific articles and a number of adverse event reports relating to HIT and HITT. Each article that Defendant submitted discusses HIT/HITT in seriously ill patients and/or patients having undergone surgery, including cardiac surgery.[8] (See Def. Ex. 4 pt. 2 to Miller Decl. at 27-31; DE 74-9.) Three of the articles submitted by Baxter to the FDA discuss thrombocytopenia and/or subsequent thrombosis in patients re-exposed to heparin. (Id. at 30-31.)

In fact, in their submission to the FDA, Baxter cited and summarized one of the articles that Plaintiffs accuse Defendant of failing to disclose. (Cf. Pls. Ex. L to Poondi Decl., with Def. Ex. 4 pt. 2 to Miller Decl. at 27-28.) That article explains that "patients typically develop thrombocytopenia while receiving heparin; the peak onset is 5 to 8 days." (Pls. Ex. L to Poondi

[8] The articles disclose, for example, patients who underwent coronary artery bypass surgeries, aortic valve replacement, mitral valve repair, and an angiographic procedure for uterine artery embolization. (See Def. Ex. 4 pt. 2 to Miller Decl. at 27-31.)

Decl. at 502.) The article also states that "[l]ow-molecular weight heparin causes immune thrombocytopenia less often than unfractionated heparin . . . ." (Id. at 505.)

With respect to platelet monitoring, Plaintiffs argue that Defendant failed to disclose the need for platelet measurement every other day. Plaintiffs, in support, point only to two scientific journal articles, the first of which recommends a patient's platelet count be monitored "every other day," and the second of which simply recommends "routine" platelet monitoring. (Pls. Exs. U and V to Poondi Decl.; DE 82-22, 82-23.) Consequently, the available research does not provide a clear-cut rule concerning at what intervals platelet counts should be measured, and Defendant's heparin label takes this into account by instructing that "Platelet counts should be obtained . . . periodically during heparin administration" and that "[t]hrombocytopenia of any degree should be monitored closely." (Def. Ex. 6 to Miller Decl. at 5.)

In view of the above, Plaintiffs have failed to present sufficient evidence to prove that Baxter engaged in intentional misconduct. No reasonable fact-finder could conclude that Defendant deliberately concealed or failed to disclose information relating to the serious side-effects of heparin, when, in reality, that information was publicly known in the medical and scientific literature. Further, Plaintiffs cannot preclude summary judgment on the issue of concealment or nondisclosure where the record evidence demonstrates that Defendant did in fact disclose much of the information regarding the risks, diagnosis, and treatment of HIT and HITT that Plaintiffs claim was intentionally kept hidden. The Court therefore finds that, as a matter of law, Plaintiffs have failed to rebut the strong presumption of adequacy with the type of evidence contemplated by the Perez exception.

b. The McDarby Exception

Plaintiffs next assert that Defendant is not entitled to the statutory presumption of adequacy because Defendant engaged in "economically-driven manipulation of the post-market regulatory process." See McDarby, 949 A.2d at 256. The significance of the McDarby exception is not immediately obvious until put in context. The case that created the exception, McDarby v. Merck & Co., Inc., was part of the fallout from the widely-prescribed drug, Vioxx. Id. at 229. The McDarby court found that Merck & Co., the manufacturer of Vioxx, was not entitled to the PLA's presumption of adequacy because, after the drug was approved and on the market, the company downplayed a known cardiovascular risk associated with Vioxx, misrepresented the results of Vioxx clinical studies, resisted a stronger warning label proposed by the FDA, and actively sought to conceal Vioxx's cardiovascular risks from physicians. Id. at 259.

Here, Plaintiffs argue that Defendant engaged in economically-driven manipulation of the post-market regulation of heparin. (Pls. Br. at 17-18.) But in support, Plaintiffs do not offer any evidence of the type considered in McDarby; in other words, Plaintiffs offer no evidence that Baxter rejected the FDA's proposed changes to heparin labeling, asked pharmaceutical representatives to avoid discussing HIT and HITT when speaking to physicians, or manipulated the conclusions of heparin clinical trials. Instead, Plaintiffs only cite to an August 22, 2008 Power Point presentation prepared by the Baxter Healthcare Pharmacy Advisory Board, which is co-chaired by two non-Baxter employees. (See Pls. Ex. CC to Poondi Decl. at 1-2; DE 82-30.) The purpose of the presentation was to get advice and feedback on Baxter's drug, argatroban, an anticoagulant indicated for the treatment of thrombosis in patients with HIT.[9] (See id. at 53.) As

[9] Baxter submitted an NDA to manufacture, market, and sell argatroban in 2008, but the FDA has not yet approved that NDA. (See Def. Exs. 1 and 2 to Miller Supp. Decl.; DE 86-2, 86-3.)

such, the presentation contains extensive information on the causes, diagnosis, and treatment of HIT. (See id. at 21-50.) Notwithstanding the educational purpose of providing this information, Plaintiffs call the presentation a "marketing campaign," and they ask the Court to infer that Baxter "hid the truth about the dangers of heparin for purposes of profit, only opting to disclose such information when it could profit from another drug[.]" (Pls. Br. at 6, 18.)

The Court will not consider this presentation as evidence properly supporting application of the McDarby exception, or draw an inference of egregious intentional misconduct from it. To begin, the presentation is dated August 22, 2008, whereas Mrs. Baker's treatment with heparin was almost a year earlier in September 2007. Plaintiffs, however, cannot satisfy the McDarby exception with "documents concerning drugs other than [heparin] and instances of conduct by [Defendant] that occurred long after" Mrs. Baker received heparin. See Bailey, 37 A.3d at 577.

Further, the Court cannot accept the conclusion that Plaintiffs have drawn from this presentation. The HIT/HITT-related information contained in the presentation was compiled and communicated not by a Baxter employee, but by a professor of clinical pharmacy at the Philadelphia College of Pharmacy. (See Pls. Ex. CC to Poondi Decl. at 21.) Further, the focus of the presentation, argatroban, had not been (and is still not) approved by the FDA such that Baxter could profit from it. It is therefore unreasonable to make the inferential leap that Baxter sought to profit from an unapproved drug with a strategically timed disclosure of the dangers of heparin. See Lexington Ins. Co. v. W. Pa. Hosp., 423 F.3d 318, 333 (3d. Cir. 2005) ("Speculation does not create a genuine issue of fact; instead, it creates a false issue, the demolition of which is a primary goal of summary judgment.") (quoting Hedberg v. Indiana Bell Tel. Co., Inc., 47 F.3d 928, 932 (7th Cir. 1995). The Court thus finds that Plaintiffs have failed

to rebut the presumption of adequacy with substantial evidence of economically-driven manipulation of the post-market regulatory process.

In sum, Plaintiffs have failed to meet their burden of coming forth with sufficient evidence to rebut the "super-presumption" of adequacy afforded to Baxter's FDA-approved heparin labeling. Pursuant to the PLA, Baxter therefore cannot be held liable for a claim of failure to warn, see N.J. Stat. Ann. 2C:58C-4, and summary judgment dismissing Counts I, II, and VIII[10] is appropriate.

B. Causation

Even if a plaintiff is able to demonstrate that a prescription drug's warning is inadequate, that plaintiff still must prove that the inadequate warning proximately caused her injury. See Campos v. Firestone Tire & Rubber Co., 485 A.2d 305, 311 (N.J. 1984). "To satisfy this burden, [a] plaintiff must show that adequate warnings would have altered her doctors' decision to prescribe [the drug]." Strumph v. Schering Corp., 606 A.2d 1140 (N.J. Super. Ct. App. Div. 1992) (Skillman, J., dissenting), rev'd 626 A.2d 1090 (1993) (adopting Judge Skillman's dissent).

Under many circumstances, "a heeding presumption may be applicable to claims of failure to warn of the dangers of pharmaceuticals . . . ." McDarby, 949 A.2d at 267. A heeding presumption allows one to presume that the plaintiff's physician would not have prescribed the drug to the plaintiff if there had been an adequate warning; in other words, the plaintiff's physician would have heeded the adequate warning. Id. The heeding presumption is rebutted, however, if the plaintiff's physician "was aware of the risks of the drug that [he] prescribed, and

[10] Count VIII, Plaintiff Bruce Baker's loss of consortium claim, is derivative of and dependent on the survival of Counts I and II. Therefore, since the Court will grant summary judgment dismissing Counts I and II, it will also grant summary judgment dismissing Count VIII.

having conducted a risk-benefit analysis, nonetheless determined its use to be warranted[.]" Id. at 268 (citing Strumph, 606 A.2d 1140).

Moreover, "a manufacturer who fails to warn the medical community of a particular risk may nonetheless be relieved of liability under the learned intermediary doctrine[11] if the prescribing physician either did not read the warning at all, . . . or if the physician was aware of the risk from other sources and considered the risk in prescribing the product." Perez, 734 A.2d at 1261 (citation omitted). In that case, the physician's conduct is the "superseding or intervening cause that breaks the chain of liability between the manufacturer and the [plaintiff]." Id.

Here, Plaintiffs suggest that there is a genuine issue of material fact as to whether Mrs. Baker's treating physician, Dr. Slater, would have prescribed heparin had there been a different warning label. (Pls. Br. at 19.) Dr. Slater testified that, hypothetically, he likely would not use a prescription drug beyond the time period indicated on the label. (Slater Dep. 92:12-93:8; Pls. Ex. E to Poondi Decl.; DE 82-6.) Plaintiffs infer that Dr. Slater therefore would have followed a heparin label containing the warnings Plaintiffs argue should have been included. Plaintiffs further suggest that Dr. Slater would have heeded warnings and instructions contained in a black box warning, a "Dear Doctor" letter,[12] or the Physician's Desk Reference.

The Court disagrees that Plaintiffs' evidence raises a genuine issue of material fact as to the element of proximate cause. Dr. Slater stated that he regularly used heparin in his cardiac

[11] The "learned intermediary" doctrine holds that "a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities." Niemiera v. Schneider, 555 A.2d 1112, 1117 (N.J. 1989). The New Jersey Supreme Court recognized that when a drug manufacturer markets their prescription drug directly to the consumer, there is a corresponding duty to warn the consumer, Perez, 734 A.2d at 1263. But that corresponding duty is not at issue in this case.

[12] "Dear Doctor" letters may be sent by drug manufacturers to physicians to inform them of important new information about a drug. See 21 C.F.R. 200.5.

surgery practice, was familiar with the risks and benefits of heparin, and was aware of HIT. (See Slater Dep. 71:8-72:24; Def. Ex. 10 to Miller Decl.; DE 74-15.) In addition, Dr. Slater stood by his decision to administer heparin to Mrs. Baker. (See id. 53:13-54:13.) "Evangeline Baker required heparin by standard medical procedure, and well documented clinical knowledge at several different time points during her operation and for several different reasons . . . She appropriately received heparin during the course of her cardiac surgery. She appropriately received heparin when she developed atrial fibrillation after her cardiac surgery." (Id. 53:13-54:7.) Where, as here, a plaintiff's physician testifies that he was "aware of the risks of the drug that [he] prescribed and, having conducted a risk-benefit analysis, nonetheless determined its use to be warranted . . . the [heeding] presumption [is] rebutted as a matter of law." See McDarby, 949 A.2d at 268 (internal citation omitted).

Further, Dr. Slater testified in his deposition that he does not read the label of drugs he prescribes often, which includes heparin. (Slater Dep. 70:23-71:7, Def. Ex. 10 to Miller Decl.) Moreover, Plaintiffs concede that Dr. Slater never testified that he would have consulted a black box warning or "Dear Doctor" letter, or that he ever reviewed the Physician's Desk Reference when prescribing heparin. Therefore, a different warning would not have made a difference in Mrs. Baker's treatment or outcome because Dr. Slater would not have reviewed it. See Perez, 734 A.2d at 1261 (explaining that a manufacturer is not liable under the learned intermediary doctrine where the plaintiff's physician did not rely on any information from the manufacturer in prescribing the drug) (citation omitted).

Finally, it is undisputed that, despite Dr. Slater's order, the staff at Morristown Memorial Hospital failed to follow its own heparin treatment protocol. (Pls. RSUMF ¶ 44; Def. SUMF ¶ 44.) Had the hospital staff followed the treatment protocol, Mrs. Baker's blood platelet levels

would have been monitored every three days during heparin administration. And, had that monitoring occurred, Mrs. Baker's physicians would have discovered the onset of HIT sooner. (See Shohet Expert Report at 9; Pls. Ex. H to Poondi Decl.; DE 82-9.)

Plaintiffs' expert, Dr. Stephen B. Shohet, attributed Mrs. Baker's injuries to "defects in medical management," including the failure to monitor Mrs. Baker's platelet count between September 11th and September 14th. (Id. at 8.) While finding the lack of detail in the heparin label regarding HIT in cardiac surgery patients "relevant" to the defects in medical management, Dr. Shohet nevertheless concluded that had the hospital staff measured Mrs. Baker's platelet level consistent with its protocol, "Mrs. Baker's subsequent HIT would probably have been detected substantially earlier[.] Heparin would have been discontinued; HIT progression to HITT would have been averted, and much of the long series of progressive morbidity, including sequential amputations would not have occurred." (Id. at 8, 9.) Dr. Shohet affirmed this opinion during his deposition, testifying that had the hospital staff monitored on the third day of heparin administration, according to hospital protocol, Mrs. Baker's injuries "would have been substantially mitigated" with a "good chance of avoiding the amputation." (Shohet Dep. 223:21-224:25; Def. Ex. 11 to Miller Decl.; DE 74-16.) Therefore, Plaintiffs have failed to raise a genuine issue of material fact that it was the heparin labeling, as opposed to the failure of the hospital to follow its treatment protocol, that was a "substantial factor in causing or exacerbating" Mrs. Baker's injuries. James v. Bessemer Processing Co., 714 A.2d 898, 909 (N.J. 1998).

Ultimately, Plaintiffs cannot demonstrate that the alleged inadequacy of Defendant's heparin labeling resulted in Mrs. Baker's injuries. Because Dr. Slater was aware of and understood the risks of heparin, and did not choose to read heparin's warning label or any

additional information from Defendant, no reasonable jury could conclude that a different label would have altered Dr. Slater's decision to administer heparin. Lastly, Mrs. Baker cannot demonstrate that it was the heparin label, rather than the hospital's failure to monitor her platelet levels, that was the substantial factor in causing her blood clots, gangrene, and eventual amputations. As such, summary judgment dismissing Counts I, II, and VIII is also appropriate because Plaintiffs have failed to demonstrate sufficient evidence to raise a genuine issue of material fact as to the element of proximate cause.

IV. CONCLUSION

For the reasons above, the Court grants Defendant's Motion for Summary Judgment and dismisses Counts I, II, and VIII of Plaintiffs' First Amended Complaint. An appropriate order is filed herewith.

Dated: August 21, 2012

/s/ JOEL A. PISANO
United States District Judge